REMARKS/ARGUMENTS

Claims 18-24, 38 and 39 are pending in this application. Claims 1-17 have been canceled. No claims have been amended. Claim 39 is new. Claims 25-37 have been withdrawn.

Claims 18-24 and 38 were rejected for obviousness over Krikorian (4,541,417) as being obvious to one of ordinary skill in the art. The Office Action concedes that Krikorian does not determine whether a value corresponding to the time between successive pairs of signal peaks exceeds a preceding value, or a preceding value averaged over a plurality of heart beats by more than a defined amount. However, this was viewed to be obvious to a person of ordinary skill in the art since it is known in the art that such a determination would provide the predictable results pertaining to utilizing a threshold setting used for only obtaining optimal pulses measured by a sensor so as to calculate an adjustable time delay response from the pulse in order to further provide a certain amount of counterpulsation which induces blood to flow into the coronary arteries and to increase the venous return, thus invoking pumping assistance to the heart.

Krikorian teaches a coronary augmenter capable of providing electrical stimulation to a person in accordance with the counterpulsation mode; i.e. Krikorian discloses an apparatus in which a person is permanently stimulated with electrical stimulation relative to the patient's heart beat.

A person's heart typically beats with a frequency of 60 beats per minute (bpm) to 170 bpm depending on the activity the person is engaged in; e.g. a person running slowly at a relatively constant speed will have a relatively constant heart rate of e.g. 130 bpm. On treating a patient Krikorian relies on the fact that a patient lying down for treatment will have a relatively constant heart rate. Krikorian describes a coronary augmenter which actively measures a patient's heart beat and transmits signals to the patient in the counterpulsation mode relative to a heart rate previously measured by a medical practitioner. To do this the medical practitioner sets parameters related to the measured heart rate relative to an R-R Pulse of the patient in question, e.g. using the variable pulse delay timer 136 etc., to ensure that the coronary augmenter of

Krikorian stimulates the patient in the counterpulsation mode at a set delay every time the monitor 14 detects a heart beat.

In general, the present invention is based on the recognition that cardiac patients requiring treatment in the counterpulsation mode inherently suffer from arrhythmia, i.e. a very non-rhythmic heart rate. Krikorian does not discuss the possibility of such a state of arrhythmia being present.

In particular, the present apparatus defined by independent claim 18 is directed to an apparatus which is used to treat a patient on a long-term basis while going about his normal routines. This means that the apparatus is not designed to and does not operate with a constant heart rate, but rather with a substantial variation over a wide range of heart rates. Normally the apparatus is used to treat patients with some degree of coronary problem, and this itself means that the range of heart rates occurring is relatively large. A person with coronary disease will typically be having a high and irregular heart rate while climbing stairs, for example. Moreover, it has also been found that if patients suffering from arrhythmia are provided with electrical stimulations during a state of arrhythmia this can have adverse effects.

For this reason, the present electrotherapy apparatus has certain inbuilt maximum and minimum permissible technical limits for the heart rate of a person to be treated, for example a minimum limit of 30 bpm and maximum limit of 250 bpm. If the detected heart rate lies outside of these limits, possibly due to arrhythmia, then it is clear that the apparatus cannot cope with such a strange heart rate and no electrical stimulation will be generated.

Furthermore, it will generally be preferable to set maximum and minimum permissible selected limits which are tighter than the technical limits referred to above. For example, for a particular patient, the treating physician could select a lower limit of 40 beats per minute and an upper limit of 170 beats per minute, thus taking a conscious decision not to treat a patient when the heart rate falls outside of these limits. Thus the processor of the electrotherapy apparatus will also compare whether the value determined for the heart rate lies within or outside of the maximum and minimum permissible selected limits.

As mentioned earlier, the Office Action asserts that the apparatus of Krikorian is capable of carrying out the steps initiated by the processor required by claim 18 and cites several passages of Krikorian which were viewed as disclosing the features of the processor.

The first step a) of the processor of claim 18 is adapted to make a determination for successive pairs of signal peaks of a value corresponding to the time between the successive pairs of signal peaks and thus to the person's heart rate.

In the Office Action, Krikorian was viewed as disclosing this step by using the Comparator 142. In actual fact, however, this comparator is used to determine if a heart beat was measured or not, and if a heart beat was measured this starts the counter 132 associated with the variable pulse delay timer 136 of Krikorian, which then initiates a patient's stimulation. Thus, Krikorian does not make a determination for successive signal peaks and thereby determine a value corresponding to the time between the successive pairs of signal peaks. This is only done at the beginning of the therapy session by the medical practitioner via the heart rate monitor 14 to set the variable pulse delay timer 136.

In this context, applicants further point out that Krikorian does not even mention the possibility of setting technical limits to the apparatus, let alone that a medical practitioner can set maximum and minimum permissible limits. These limits are selected in accordance with claim 18 so that the claimed apparatus can distinguish between a state of arrhythmia and a normal state of the heart rate in subsections b) and c) of claim 18. Moreover, since claim 18 requires the apparatus to have a microprocessor which automatically performs the therapy on the basis of the measured heart rate due to routines stored in a memory associated with the microprocessor, a medical practitioner can no longer erroneously program a wrong delay for a patient, as the device itself carries out this operation for him.

Thus, in addition to the fact that Krikorian does not disclose a processor, be it in the form of a microprocessor or a microcontroller, Krikorian also does not disclose or in any manner suggest the steps a) to n) of claim 18, which are all based on measuring the time between successive signal peaks and comparing these to technical and/or practical limits set individually

for each patient. Based on what Krikorian teaches, a person of ordinary skill in the art would neither consider the reference to suggest the very different apparatus, nor would the person's education and professional background lead him to the apparatus of claim 18.

Accordingly, claim 18 is not obvious over Krikorian and the skill of a person of ordinary skill in the art.

Claims 19-24 and 38 are allowable because they depend from allowable parent claim 18.

New independent claim 39 fully tracks the working of independent claim 18. Claim 39 is therefore allowable for the same reasons why claim 18 is allowable.

Claim 39 additionally requires in subparagraph g) that the signal processor is adapted to "suppress said trigger if a state of arrhythmia is detected from the successive pairs of signal peaks". For the reasons discussed earlier, this is not disclosed or in any form suggested by Krikorian and, indeed, runs counter to Krikorian's requirement that the patient be stimulated in the counterpulse mode at a set delay every time the monitor detects a heart beat. Further, a person of ordinary skill in the art would not even consider to employ the feature of subparagraph g) of claim 39 because that would run counter to the disclosure of Krikorian and, indeed, render Krikorian unusable for its intended purpose.

For this additional reason, new claim 39 is not obvious over Krikorian.

CONCLUSION

In view of the foregoing, applicants submit that this application is in condition for allowance, and a formal notification to that effect at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 273-4730 (direct dial).

Respectfully submitted,

/J. Georg Seka/

J. Georg Seka
Reg. No. 24,491

KILPATRICK TOWNSEND & STOCKTON LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JGS:jhw
63259175 v1